REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. DISPOSITION OF THE CLAIMS

Claims 1-2, 22-29, 31-33, and 38-45 are under examination in this application. Claims 30 and 34-37 are withdrawn as non-elected.

Claim 1 is amended to introduce the limitations of claim 31. Claim 31 has been canceled. Claims 32-33 have been amended to depend from claim 1 instead of canceled claim 31. No new matter has been added.

II. ANTICIPATION

Claims 1-2, 22-29, and 38-42 stand rejected as anticipated under 35 U.S.C. § 102(b) over WO 01/77181 as evidenced by counterpart US 2003/0175969.

Applicants respectfully traverse this ground of rejection.

To further prosecution, however, Applicants have obviated this rejection by incorporating the limitations of claim 31 into claim 1, such that amended claim 1 corresponds to claim 31 redrafted in independent form.

Claim 1 now recites the limitation "wherein said human, humanized, or chimeric monoclonal antibody is an anti-HLA-DR antibody" of claim 31. WO 01/77181 does not disclose this feature, and the Office omitted claim 31 from the claims rejected as anticipated.

The anticipation rejection is also obviated for Claims 2, 22-29, and 38-42, because these claims depend directly or indirectly from claim 1 and thus also now contain the newly-added limitation of claim 31.

Accordingly, this ground of rejection should be withdrawn.

III. OBVIOUSNESS

Claims 1, 31-33, and 45 stand rejected under 35 U.S.C. § 103(a) over US 6,894,149 ("Tso") and EP 1229125 ("Ogawa").

Applicants traverse the obviousness rejection because no proper prima facie case of obviousness had been made out, and because unexpected results in the specification effectively rebut any such prima facie case.

A. The Art Of Record Establishes No Prima Facie Case of Obviousness

Applicants submit that no proper prima facie case of obviousness had been made out, because Ogawa does not solve any problem disclosed in Tso.

According to Ogawa, the presence of serum introduces problems related to inconsistency and yield (column 1, lines 46-48). To solve these problems, Ogawa discloses a method for producing polypeptides using rat cells adapted to a medium that is serum-free (see Abstract).

Tso does not disclose any such problem. Instead, Tso discloses using lipid raft immunization as preferred method (column 6, lines 34-45). A skilled artisan would thus have no reason to use the YB2/0 cells of Ogawa to produce the antibodies of Tso.

The Office asserts that a skilled artisan would use the YB2/0 host cells of Ogawa, because Ogawa discloses that antibodies made in YB2/0 host cells "have a higher antibody-dependent cell-mediated cytotoxic activity (ADCC). The Office mischaracterized Ogawa in this regard, because Ogawa disclose ADCC that is merely "high" and does not disclose ADCC that is "higher" than any reference ADCC (see Abstract, lines 1-4 from bottom, column 1, lines 16-18, column 17, lines 19-21, and column 25, lines 25-28). By referring to the ADCC as "high", Ogawa merely intended to show that the ADCC was not unacceptably low in antibodies obtained using Ogawa's method. A person of ordinary skill in the art would not recognize Ogawa as disclosing any improvement in ADCC.

Ogawa does not appear to disclose any ADCC data. Instead, Ogawa provides production rates in Table 1 for the antibody produced. Similarly, Ogawa discloses in Figures

1-3 data for cell density and antibody concentration as a function of time, to demonstrate the viability of Ogawa's method.

Accordingly, Ogawa and Tso do not properly make out a prima facie case of obviousness, and the rejection should be withdrawn.

B. Unexpected Results In The Specification Provide Rebuttal Evidence

Evidence pertaining to secondary considerations (including unexpected results) must be taken into account whenever present. M.P.E.P. § 2145, citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007). Office personnel should consider all rebuttal arguments and evidence presented by applicants, and it is legal error not to consider evidence presented. M.P.E.P. § 2145, citing *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) and *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996).

The Office failed to recognize unexpected results in the invention's "ability to induce a rate of production of at least one cytokine by the Jurkat CD16 cell or a CD16 receptor-expressing effector cell of the immune system of greater than 60%, compared with the same antibody produced in a CHO line or with a commercially available homologous antibody"

The Office recognizes that neither of Tso and Ogawa discloses any "ability to induce a rate of production of at least one cytokine by the Jurkat CD16 cell or a CD16 receptor-expressing effector cell of the immune system of greater than 60%, compared with the same antibody produced in a CHO line or with a commercially available homologous antibody". Instead, the Office asserts that the quoted limitation is "intrinsic characteristics" of the antibody (Office Action, page 7, lines 6-12) and concedes that such feature was "unknown at the time" (Office Action, page 7, line 20).

The Office recognizes that the present specification discloses the particular claimed feature of "ability to induce a rate of production of at least one cytokine by the Jurkat CD16 cell or a CD16 receptor-expressing effector cell of the immune system of greater than 60%, compared with the same antibody produced in a CHO line or with a commercially available homologous antibody". Office Action, page 7, lines 12-14.

This recited property is an unexpected result that rebuts any prima facie case of obviousness. Even if a person of ordinary skill in the art were led to combine Tso with Ogawa, which Applicants vigorously dispute, such a skilled artisan would have no basis to expect the advantageous feature discovered by Applicants of "ability to induce a rate of production of at least one cytokine by the Jurkat CD16 cell or a CD16 receptor-expressing effector cell of the immune system of greater than 60%, compared with the same antibody produced in a CHO line or with a commercially available homologous antibody".

Certainly, the very nature of unexpected results is the state of being unknown, and is evidence of nonobviousness. *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.").

As noted above in traversing prima facie obviousness, Ogawa does not disclose "higher" ADCC and does not appear to disclose any ADCC data at all. Instead, Ogawa alleges "high" ADCC to avert doubt about the viability of the antibodies produced by Ogawa's serum-free method.

Accordingly, this ground of rejection should be withdrawn.

IV. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING (ODP)

The claims stand provisionally rejected for obviousness-type double patenting over specific claims of copending applications 10/551,819 and 10/575,218 and 11/039,877.

Applicants request that this ground of rejection be held in abeyance pending indication of allowable subject matter.

CONCLUSION

Applicant request entry of this Reply to place the present application in condition for allowance.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 31-JUL-2009 By _____

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4059
Facsimile: (202) 672-5399

Rouget F. Henschel
Attorney for Applicant
Registration No. 39,221